

EXHIBIT 19

MiniScript

of the deposition of

Natalie Nelson-Ling

(Volume I)

Taken October 21, 2016

in the matter

United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington and Wisconsin; the District of Columbia, the City of Chicago and ex rel. Oswald Bilotta,

v

Novartis Pharmaceuticals Corporation

Case Number: 11 CIV 0071 (PGG)



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<p>1 UNITED STATES DISTRICT COURT 2 SOUTHERN DISTRICT OF NEW YORK 3 -----x 4 UNITED STATES OF AMERICA, the States 5 of CALIFORNIA, COLORADO, CONNECTICUT, 6 DELAWARE, FLORIDA, GEORGIA, HAWAII, 7 ILLINOIS, INDIANA, IOWA, LOUISIANA, Case Number 8 MASSACHUSETTS, MICHIGAN, MINNESOTA, 11 Civ. 0071 (PGG) 9 MONTANA, NEVADA, NEW HAMPSHIRE, 10 NEW JERSEY, NEW MEXICO, NEW YORK, 11 NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, 12 TENNESSEE, TEXAS, VIRGINIA, WASHINGTON 13 and WISCONSIN; the DISTRICT OF COLUMBIA, 14 the CITY OF CHICAGO and ex rel. OSWALD 15 BILOTTA, 16 Plaintiffs and Relator, 17 -against- 18 NOVARTIS PHARMACEUTICALS CORPORATION, 19 Defendant. 20 -----x 21 October 21, 2016, 10:09 am 22 Deposition of NATALIE ELAINE NELSON-LING 23 lipka.com, inc. 24 888.lipka.com 25 transcripts@lipka.com</p>	<p>1 A P P E A R A N C E S (Continued): 2 3 SHEPHERD FINKELMAN MILLER & SHAH, LLP. 4 Attorneys for Relator, Oswald Bilotta 5 65 Main Street 6 Chester, Connecticut 06412 7 BY: LAURIE RUBINOW, ESQ. 8 9 10 ALSO PRESENT: 11 SARA M. ZAUSMER, Director, 12 Novartis Services, Inc. 13 ROBERT CALVERT, The Videographer 14 NICK LUSSIER, Paralegal, 15 Shepherd Finkelman Miller & Shah, LLP. 16 17 18 19 20 21 22 23 24 25</p>
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<p>1 APPEARANCES: 2 U.S DEPARTMENT OF JUSTICE 3 U.S. ATTORNEY'S OFFICE 4 SOUTHERN DISTRICT OF NEW YORK 5 Attorneys for Plaintiffs 6 86 Chambers Street 7 New York, New York 10007 8 BY: JENNIFER JUDE, ESQ. 9 10 CRAVATH SWAINE & MOORE, LLP. 11 Attorneys for Defendant 12 Worldwide Plaza 13 825 Eighth Avenue 14 New York, New York 10019-4775 15 BY: BENJAMIN GRUENSTEIN, ESQ. 16 AND: OLIVER ROCOS, ESQ. 17 18 SKADDEN ARPS SLATE MEAGHER & FLOM, LLP. 19 Attorneys for The Witness 20 4 Times Square 21 New York, New York 10036 22 BY: STEVEN R. GLASER, ESQ. 23 AND: YOOSUN KOH, ESQ. 24 25</p>	<p>1 INDEX 2 Witness: Natalie Elaine Nelson-Ling Page 3 By: Ms. Jude 8 4 By: Mr. Gruenstein 242 5 By: Ms. Jude 264 6 7 E X H I B I T S 8 Nelson-Ling Exhibit Page 9 GX-1 Natasha Nelson's LinkedIn 43 10 Profile 11 GX-2 Document Bates stamped 145 12 NPCLSV_LIT003486097 through 13 NPCLSV_LIT003486142 14 GX-3 Slide presentation entitled 181 15 "2008 Audit of Sales 16 Representatives Interactions 17 With Healthcare Professionals" 18 Bates stamped 19 NPCLSV_LIT0001591473 through 20 NPCLSV_LIT001490) 21 GX-4 Document Bates stamped 204 22 NPCLSV_LIT66834049 through 23 NPCLSV_LIT66834054 24 25 (CONTINUED)</p>
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<p>1 to keep track of its speaker bureau, where the 2 money was being spent, what was being done, for 3 many reasons; ranging from, it was their money 4 and, you know, it was fiscally responsible. 5 They wanted to make certain that the company was 6 ethically responsible.</p> <p>7 They wanted the speaker bureau to 8 be effective. You know, all the kinds of 9 information that Cindy was in charge of 10 collecting, all went to a corporate goal of 11 spending the money right, doing the right thing, 12 getting information out to doctors, so that they 13 could know how to treat their patients with 14 Novartis drugs, and so that doctors could 15 understand, also, the medical side of the 16 disease that the Novartis drugs treated. And 17 so, a very important component was the medical 18 education.</p> <p>19 Q. Within Novartis, were there other 20 departments or bodies, besides the ethics and 21 compliance department, that had a responsibility 22 for making sure that Novartis's promotional 23 events complied with the law?</p> <p>24 A. If I understand what you're asking, 25 everyone at Novartis was responsible for making</p>	<p>1 Q. Does that mean healthcare 2 providers? 3 A. It does. 4 Q. What do you understand a roundtable 5 to be? 6 A. A roundtable is, as I understand 7 it, when the doctors are -- are sitting around a 8 table, as opposed to somebody standing up and 9 presenting, and I think it's -- it's less 10 formal. 11 Q. Does it have the other 12 characteristics of the speaker program? 13 A. It could. I was not involved in 14 auditing, monitoring or doing investigations, 15 that I recall, where I got into the detailed 16 aspects of what a roundtable was. 17 Q. While you were at Novartis, did 18 someone else have responsibility for 19 investigations, auditing and monitoring of 20 roundtables? 21 A. No. It would have been me. 22 Q. So if you weren't doing it, then no 23 one was doing it? 24 A. Investigations, I do not recall me 25 having a case regarding an investigation of a</p>
<p>1 certain that -- that they complied with the law. 2 So I can't name you individual departments. 3 Q. Were there other departments, 4 besides ethics and compliance, that had that as 5 their primary role? 6 A. The law department would have. And 7 there were probably other departments that I -- 8 I can't think of right now. 9 Q. And just to make sure we're on the 10 same page. Could you define what you understand 11 a speaker program to be? 12 A. A speaker program is a promotional 13 program in which a physician -- in which a 14 healthcare provider, be it a physician, a nurse 15 practitioner, a pharmacist, has been carefully 16 trained and hired to present the promotional 17 review committee approved deck, and, based upon 18 their training, provide clinical information and 19 be able to answer pertinent questions. 20 Q. You said provide clinical 21 information and be able to answer pertinent 22 questions. Is there a particular audience part 23 of the definition of speaker program? 24 A. The audience would be to other 25 HCPs.</p>	<p>1 roundtable. We audited speaker programs 2 randomly, and I don't remember any of us going, 3 randomly picking something that turned out to be 4 a roundtable, and I'm not the best one to ask on 5 whether we ever did an audit about a roundtable, 6 because I just don't remember any more. 7 Q. Who would be the best one to ask 8 about that? 9 A. It would probably be David 10 Hollasch. 11 Q. So sitting here today, you don't 12 remember doing any investigations, any auditing 13 or any monitoring while at Novartis that was 14 focused on a roundtable event? 15 MR. GRUENSTEIN: Objection, lacks 16 foundation. Assumes there were roundtable 17 events during this period. 18 A. I must have, but I cannot recall. 19 Q. Okay. So that's a -- let me repeat 20 my question. 21 So sitting here today, you don't 22 recall doing any investigations, auditing or 23 monitoring of roundtable events? 24 MR. GRUENSTEIN: Same objection. 25 A. I don't recall right now. If you</p>

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<p>1 experience working at Daiichi Sankyo. 2 Q. Is there anything in particular 3 about your experience working at Daiichi Sankyo 4 that led you to add speaker programs to Novartis 5 as a risk assessment list? 6 A. I would say that the CIA that 7 Daiichi Sankyo signed in January of 2015 8 reflected many of the issues that we had been 9 seeing at Daiichi Sankyo, which left me without 10 any specific knowledge or hints even within the 11 industry to put that at the top of my list. 12 Q. Could you describe in general terms 13 what those issues were? 14 A. The issues at Daiichi Sankyo? 15 Q. Yes. 16 A. The issues at Daiichi Sankyo 17 concerned meal costs, promotional decks, 18 locations, those kinds of areas. And so, when I 19 went to Novartis, without having any specific 20 knowledge of Novartis, we simply added in that 21 we would do -- randomly attend 45 speaker 22 programs within, basically, the period of Q3 23 20 -- no, 2008. 24 Q. Was that the audit that was later 25 called the 2008 audit of interactions with HCPs?</p>	<p>1 me within 24 hours; so that, within a very short 2 time frame, I could be able to call people and 3 start doing the investigation. 4 Q. That person who was in charge of 5 investigations when you arrived, that you just 6 referred to, was that Maria Woods? 7 A. Yes. 8 Q. Can you describe what you mean by, 9 she was very behind? 10 A. When I came to Novartis, they 11 didn't have a good system for counting and 12 tracking complaints, and Maria's office was 13 filled with file folders. So we took those file 14 folders, and one by one went through, and, to 15 the extent we could investigate them, we did. 16 If we had to close them out because the 17 employees were no longer there, we did; but we 18 went through all the file folders that we found. 19 Q. Approximately how many 20 investigations was Ms. Woods handling at the 21 time that you arrived? 22 A. I don't know how many she was 23 handling. I know that there were hundreds of 24 file folders. 25 Q. Does each of those file folders</p>
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<p>1 A. I believe so. 2 Q. Let's look back at GX-1. Do you 3 see where it says, "Revised and strengthened the 4 compliance investigations systems and 5 protocols"? 6 A. No. 7 Q. On the second line. 8 A. Oh. Okay. Mid-sentence? 9 Q. Yes. 10 A. "Revised and strengthened the 11 compliance investigations systems and 12 protocols." Yes, I see it. 13 Q. Could you describe what 14 specifically you did for Novartis? 15 A. When I arrived at Novartis, they 16 had a person in the compliance department that 17 was doing investigations. She was very behind 18 in her investigations, and I revised how we 19 would do investigations, the priorities for 20 addressing them, the time lines for handling 21 them, and I made it my -- my job to teach people 22 that received a complaint from someone to say 23 things like, thank you for bringing this to our 24 attention, I'm going to refer it to compliance, 25 and I taught people to refer the complaints to</p>	<p>1 relate to an individual investigation or more 2 than one investigation? 3 A. Generally, one investigation. 4 Maybe two. But, generally one. 5 Q. Was Ms. Woods the only employee at 6 Novartis who had a responsibility for doing 7 investigations at the time that you arrived? 8 A. I don't think she was the only 9 employee in charge of doing investigations. She 10 was the only employee that worked for Julie Kane 11 that was doing investigations. 12 Q. So she had a backlog of several 13 hundred investigations, is that correct? 14 A. Yes. 15 Q. And, what ended up happening to all 16 of those investigations? 17 A. We opened them, read them, 18 investigated them, and either closed them out 19 because the people were gone. Investigated 20 them. They were either substantiated, not 21 substantiated, unable to substantiate, but, we 22 resolved every single one of them. 23 Q. Approximately what portion of them 24 were mooted by the fact that the employee was 25 gone?</p>
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<p>1 rewrite this differently. So we talked to him 2 about how you might write this, or things that 3 you might add to it.</p> <p>Q. Were you attempting to reduce ambiguity on the policies?</p> <p>6 A. In my view, I was.</p> <p>Q. Did you find the policies that Marty had written to be ambiguous?</p> <p>9 A. I found the policies that Marty had 10 written were understood better by non-lawyers 11 than lawyers, and understood better by some 12 people than others. I found that it was a mixed 13 bag.</p> <p>Q. Did they -- strike that. Did the policies that Marty had written related to healthcare compliance leave room for interpretation?</p> <p>18 MR. GRUENSTEIN: Objection; 19 leading.</p> <p>20 A. Yes. He viewed policies like a 21 constitution. I viewed -- I viewed policies 22 like a set of rules that you have for your kids. 23 You know, you brush your teeth, you do this. 24 And my understanding of rules are that it's 25 specific like that. Wake up in the morning and</p>	<p>1 and eventually went over Marty's head to Julie 2 Kane to effect different training and 3 definitions on policies.</p> <p>Q. Why did you have to go above Marty's head to Julie Kane to do that?</p> <p>6 A. Because Marty and I -- Marty had a 7 different philosophy than I did, that's all it 8 was. It was a philosophical difference. And 9 Julie Kane was our supervisor. And, if I 10 couldn't reach agreement with Marty, then Marty 11 and I went together to Julie, and eventually we 12 created training that defined items that I felt 13 had not been as clear before, because of the 14 difference in philosophy on how to write a 15 policy.</p> <p>Q. What did you observe during that Q3 audit that led you to your belief that others had difficulty understanding the policies?</p> <p>19 A. That is a question that has many, 20 many parts to it, so let me try to parse it out. 21 In the Q3 audit, we did 42 ride-alongs and 22 attended, randomly, 45 different speaker 23 programs. The things that we saw were -- on 24 speaker programs, let's start there. 25 People didn't understand how to run</p>
<p>1 brush your teeth, make up your bed, be dressed 2 in clothes that match. You know, specifics, 3 right?</p> <p>4 Marty -- Marty -- Marty felt that 5 the rule would be, wake up in the morning, get 6 ready and come down. And it's just two 7 different philosophies. It's not that his 8 philosophy was bad or my philosophy was bad. 9 It's just that we had different philosophies on 10 how to get to the same place of getting the kid 11 downstairs.</p> <p>12 MR. GRUENSTEIN: Maybe you have 13 different types of children.</p> <p>14 THE WITNESS: Yeah, we probably 15 did.</p> <p>Q. Did you and David Hollasch advise Mr. Putenis on policy changes because you felt it would make the policies more effective?</p> <p>19 MR. GRUENSTEIN: Objection, 20 mischaracterizes the word advise.</p> <p>21 A. I felt, based upon what I saw 22 during the Q3 2008 audits, that other people 23 that worked for Novartis shared my view on 24 having a difficulty understanding the compliance 25 policy, and, based upon that, I talked to Marty,</p>	<p>1 a speaker program to reflect the financial 2 controls that Novartis management wanted. 3 People didn't think about some of the easy 4 controls, such as, count the number of heads, 5 compare it to how many meals you've been charged 6 for, a simple thing, but, in our audit we found 7 routinely the restaurants were sneaking in one, 8 two, three extra meals. 9 If you haven't counted heads, if 10 you don't get the receipt at the end and count 11 the number of meals, it's easy to have -- to be 12 cheated. 13 Of all the findings from our audit, 14 that was, I think, the one that upset management 15 the most, because they wanted a tight financial 16 control.</p> <p>17 For speaker programs, we found that 18 it wasn't clear that the speaker had to use the 19 promotional review committee approved deck 20 without changes; changes being adding, deleting, 21 modifying the deck. They didn't understand that 22 what the Novartis policy said was, have a room 23 conducive to a medical discussion. People 24 interpreted that as everything from a room with 25 four walls, to a unique table in the middle of a</p>

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<p>1 busy restaurant.</p> <p>2 And, because the policy was written</p> <p>3 as a constitution, each person was their own</p> <p>4 state, and each person had their own</p> <p>5 interpretation of how they were complying. So</p> <p>6 that's just examples on speaker programs.</p> <p>7 There's more speaker programs, but, let me move</p> <p>8 to ride-alongs and try to explain that.</p> <p>9 One of the things we were looking</p> <p>10 at in the ride-alongs was, did the training that</p> <p>11 was done, did it transfer and translate</p> <p>12 practically into reps knowing what to do. And</p> <p>13 so, we were checking things like, did the sales</p> <p>14 rep provide indication and limitations of use,</p> <p>15 safety; did they provide fair balance, advise of</p> <p>16 the black box warning on, for example, Diovan,</p> <p>17 did they have a full and fair promotional</p> <p>18 discussion with the physician, with the</p> <p>19 healthcare provider. We were looking at those</p> <p>20 kinds of things.</p> <p>21 And, basically, what David and I</p> <p>22 had done was that, we wanted to make certain</p> <p>23 that we were singing from the same hymnal. And</p> <p>24 so, before we did any of these ride-alongs or</p> <p>25 attended speaker programs, we came up with</p>	<p>1 MS. JUDE: Yes. Absolutely.</p> <p>2 THE VIDEOGRAPHER: This marks the</p> <p>3 end of tape number 1. We are going off the</p> <p>4 record. The time is 11:40.</p> <p>5 (Off the record)</p> <p>6 THE VIDEOGRAPHER: Here marks the</p> <p>7 beginning of tape number 2. We are back on the</p> <p>8 record. The time is 11:56.</p> <p>9 Q. Okay. So, Ms. Nelson-Ling, you</p> <p>10 said earlier that one of the things that led you</p> <p>11 to put speaker programs on your risk assessment</p> <p>12 outline when you got to Novartis was your</p> <p>13 experience at Daiichi Sankyo with respect to</p> <p>14 meal costs, promotional decks and venues. Do</p> <p>15 you remember saying that?</p> <p>16 A. Yes.</p> <p>17 Q. So when you conducted that Q3 audit</p> <p>18 while you were at Novartis, you found issues</p> <p>19 with respect to those three things, is that</p> <p>20 right?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Was there anything else that</p> <p>23 led you to put speaker programs on your risk</p> <p>24 assessment outline, other than your experience</p> <p>25 at Daiichi Sankyo, and also the trainings that</p>
<p>Page 65</p> <p>1 checklists that we used, so that we always</p> <p>2 looked at exactly the same things, and during</p> <p>3 the ride-along checked it off. Did they say the</p> <p>4 indication? Check yes, check no.</p> <p>5 Did they say the limitations of</p> <p>6 use? Yes, no. Did they give a piece of ISI?</p> <p>7 Yes, no. Did they use a promotional detail</p> <p>8 piece? Yes. If so, what was it?</p> <p>9 Now, so that we were looking at</p> <p>10 exactly the same thing. So that, whether it was</p> <p>11 David going out or me going out, Rebecca going</p> <p>12 out, no matter who it was, we came up with the</p> <p>13 same answers, and so that gave us consolidated</p> <p>14 information.</p> <p>15 Q. Before you did that Q3 audit with</p> <p>16 those checklists, had Novartis done an audit of</p> <p>17 speaker programs before?</p> <p>18 A. I do not know.</p> <p>19 Q. You created those checklists for</p> <p>20 the audit?</p> <p>21 A. Yes.</p> <p>22 Q. So those checklists -- at least no</p> <p>23 one used your checklist before you?</p> <p>24 A. Nobody used our checklist before.</p> <p>25 THE WITNESS: Could I take a break?</p>	<p>Page 67</p> <p>1 you said that you did at food, drug and law</p> <p>2 trainings, et cetera?</p> <p>3 A. Not that I recall specifically. It</p> <p>4 was really my experience and the training,</p> <p>5 trainings at FDLI, and also our outside counsel</p> <p>6 have these, you know, conferences every so</p> <p>7 often. A half day conference in New York City,</p> <p>8 and you go in and they train on important</p> <p>9 topics.</p> <p>10 Q. So after the results for that --</p> <p>11 from that -- let's start over again. After the</p> <p>12 results from that Q3 audit came in, did you</p> <p>13 continue to think that speaker programs belonged</p> <p>14 on that risk assessment list?</p> <p>15 A. Yes.</p> <p>16 Q. And why was that?</p> <p>17 A. We found issues that we needed to</p> <p>18 remediate.</p> <p>19 Q. What else was on that list besides</p> <p>20 speaker programs?</p> <p>21 A. What do you mean? I don't</p> <p>22 understand the question.</p> <p>23 Q. So my understanding of the risk</p> <p>24 assessment list that you were describing, was</p> <p>25 that it listed things that the organization had</p>

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<p>1 what a speaker program is up to the 2 representatives?</p> <p>3 MR. GRUENSTEIN: Objection; 4 leading.</p> <p>5 A. I felt that it did because, 6 philosophically, I believe in set rules. 7 Philosophically, other people, particularly 8 Marty, felt that everyone knows what a place 9 that's conducive to a medical education, you 10 know, medical discussion means.</p> <p>11 It was a problem with 12 interpretation. And I think that there were 13 some sales reps that are more like me than 14 Marty, and, when I read conducive to a medical 15 discussion, heavens, most of my medical 16 discussions are in 4 by 4 rooms talking to a 17 doctor, like this (indicating), you know. 18 That's certainly not where you want to hold a 19 speaker program, you know.</p> <p>20 It depends upon the interpretation. 21 I disagreed with many of the sales reps' 22 interpretation.</p> <p>23 Q. Did you think that many of the 24 sales reps were not complying with the 25 guidelines based on the interpretation they had</p>	<p>1 Tampa look at anything related to a Dr. [REDACTED]? 2 A. Yes, it did. 3 Q. What do you know about Dr. [REDACTED]? 4 MR. GRUENSTEIN: Objection; vague. 5 Q. Strike that. What actions -- 6 strike that again. What about Dr. [REDACTED] did 7 your team look at when they did the audit in 8 Tampa? 9 A. We went to a speaker program, had 10 Dr. [REDACTED], a Tampa based, I think 11 cardiologist, a Tampa based physician, who was 12 hired to give a speaker program, promotional 13 program, educational deck presentation to a 14 group of HCPs. 15 We had done some investigations 16 talking to sales reps, talking to the sales rep 17 looking at documents regarding the sales rep 18 that was doing the fishing boat programs. We 19 went to the program that Dr. [REDACTED] was 20 supposed to be speaking at. 21 We got there. They were sitting at 22 a large table in the middle of a restaurant with 23 no SlideDeck, eating maybe their salads, and we 24 fixed it. 25 Q. Well, just so we have something</p>
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<p>1 chosen?</p> <p>2 MR. GRUENSTEIN: Objection; 3 leading.</p> <p>4 A. No. I think that the people that 5 interpreted the guideline felt that what they 6 were doing was okay.</p> <p>7 Q. I'm wondering what you thought of 8 what they were doing, whether it was okay or 9 not?</p> <p>10 A. I thought that what they were doing 11 was not okay.</p> <p>12 Q. How many speaker program audits did 13 you or your team do in Tampa, approximately?</p> <p>14 A. At this time, I do not recall. I 15 know that we looked at the documentation from 16 many programs. I know that we attended the one 17 program. I don't know if we attended other 18 programs, because, if we did, nothing 19 interesting happened.</p> <p>20 Q. I'm trying to get a sense relative 21 to the 45 that you did in the Q3, approximately 22 how large the Tampa audit was?</p> <p>23 A. It would have been two to three 24 sales reps, two to three programs, most.</p> <p>25 Q. Did the audit that your team did in</p>	<p>1 more specific on the record, can you tell me 2 what you mean by, "we fixed it"?</p> <p>3 A. We made him go out and get his 4 computer, present the slides. We had been 5 alerted by one of the sales reps that Dr. -- 6 that the doctor liked to take an extra meal to 7 go. We -- I monitored the liquor. I didn't let 8 anything get to the table, no matter whether it 9 was ordered or not, and I had David Hollasch sit 10 next to Mrs. [REDACTED] during the program and 11 watch her advance the slides and listen to the 12 presentation.</p> <p>13 Q. Was Mrs. [REDACTED] a healthcare 14 professional herself?</p> <p>15 A. She purported to be.</p> <p>16 Q. Do you know whether she actually 17 was?</p> <p>18 A. A health -- she may have been.</p> <p>19 Q. Did anyone check to see whether she 20 was?</p> <p>21 A. We did.</p> <p>22 Q. And do you remember whether she was 23 now or --</p> <p>24 A. A healthcare professional could be 25 somebody that works in the doctor's office. And</p>
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<p>1 Anti-Kickback Statute with the scenario that I 2 gave to you, with the spouse who works in the 3 office?</p> <p>4 MR. GRUENSTEIN: Objection; 5 leading. As if God cares about the 6 Anti-Kickback Statute.</p> <p>7 A. If the person doesn't get anything 8 out of the educational exchange, then I think an 9 educational exchange hasn't -- hasn't occurred.</p> <p>10 Q. So is that a yes or a no, with 11 respect to the Anti-Kickback Statute?</p> <p>12 MR. GRUENSTEIN: Objection to form.</p> <p>13 A. I think that if they don't get -- 14 if they're not capable of getting anything from 15 it, and that would have to be individual, and 16 based upon the individual deck and the 17 individual itself, then I think it has a 18 potential to be an Anti-Kickback.</p> <p>19 Q. I'm going to mark another exhibit 20 for you. This is going to be Nelson-Ling GX-2. 21 (Nelson-Ling Exhibit GX-2, Document 22 Bates stamped NPCLSV_LIT003486097 through 23 NPCLSV_LIT003486142, marked for identification.)</p> <p>24 MS. JUDE: And, for the record, 25 this is Bates stamped NPCLSV_LIT003486097</p>	<p>1 know they are under scrutiny, it is likely that 2 the Thursday dinner will be cancelled or handled 3 outside their norm. What do you recommend we 4 do?"</p> <p>5 Do you remember what this email is 6 about?</p> <p>7 A. It's about the [REDACTED] and the mini 8 audit that we did down in Tampa.</p> <p>9 Q. Then I'm going to direct you to the 10 next page, the one that ends in 6111.</p> <p>11 So Julie has replied to you, that 12 email is redacted, and then you respond back to 13 her on March 4, 2010:</p> <p>14 "Julie, David and I discussed the 15 MO for the Tampa work and recommend that we: 1) 16 attend without notice the speaker program on the 17 18th of March (arrive 15 minutes after program 18 start and simply tell Chris Tilberg that he has 19 a surprise audit by E&C) -- fly in and out."</p> <p>20 Why did you recommend this approach 21 to Julie Kane?</p> <p>22 A. To avoid having the speaker program 23 be cancelled.</p> <p>24 Q. And why were you concerned that it 25 would be cancelled?</p>
<p>1 through 6142. It's a very long email chain. 2 The topmost email is dated September 19, 2011.</p> <p>3 Q. I want to direct you to an email on 4 the page that ends in 6112. It's the little 5 number in the bottom right-hand corner.</p> <p>6 Do you see the email that says, 7 from Natasha Nelson to Julie Kane, cc'ing three 8 people, subject "Employee Interview Notice Re: 9 Interviews in Tampa"?</p> <p>10 Tell me when you find that.</p> <p>11 A. Okay.</p> <p>12 Q. Are you on the page that ends 6112?</p> <p>13 A. Yes.</p> <p>14 Q. I'm going to read the email that 15 I'm referring to into the record. It says -- 16 it's from you, right, on March 4, 2010?</p> <p>17 A. Correct.</p> <p>18 Q. "Julie, I'd like to review the 19 decision reached yesterday and our marching 20 orders for Tampa. The tactics for dealing with 21 the employees and the notice they'll receive of 22 their interviews on Friday are a concern for me. 23 I recommend that we do not give them more than a 24 night's notice to the employees in Tampa prior 25 to their Friday interviews. If the employees</p>	<p>1 A. Because people fear internal 2 audit-type events.</p> <p>3 Q. On that first email I read to you, 4 it says, "If the employees know they're under 5 scrutiny, it is likely the Thursday dinner will 6 be cancelled or handled outside their norm."</p> <p>7 A. Right.</p> <p>8 Q. What did you mean by "handled 9 outside their norm"?</p> <p>10 A. I believe that we had information 11 that they -- this was the same area where the 12 woman sales rep was doing the speaker programs 13 on the fishing boats, and we had, I don't 14 remember if it was notice from a male sales rep 15 that something strange was going on or -- I 16 don't remember how we kind of started to get 17 into this, but, we suspected that Dr. [REDACTED] 18 might not give a presentation.</p> <p>19 So we didn't want them to have 20 notice because we didn't want them -- we didn't 21 want to fly all the way to Tampa and then get a 22 totally in compliance program, if that's what 23 their -- not what their norm was.</p> <p>24 Q. Is it a best practice, when doing 25 an audit of a speaker program, to give no</p>

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<p>1 for Novartis?</p> <p>2 A. It depends what Novartis knew and 3 how they educated. It depends upon more facts.</p> <p>4 Q. Would it violate the Anti-Kickback 5 Statute for a Novartis employee, for that 6 employee to pay an honorarium to a physician 7 speaker if that speaker did not actually deliver 8 a presentation?</p> <p>9 MR. GRUENSTEIN: Objection; lacks 10 foundation.</p> <p>11 A. If -- is this going back to what 12 you were saying before, to induce the doctor to 13 write for Medicaid and Medicare?</p> <p>14 Q. Yes. All my questions in this line 15 of questioning, please assume that there's a 16 federal healthcare entity paying.</p> <p>17 A. Okay. So the question is, in a 18 Medicare -- if a Novartis employee paid a bribe, 19 like gave a \$200 gift check to a physician to 20 get them to prescribe for a Medicare, Medicaid 21 patient a Novartis drug? Yes.</p> <p>22 Q. And if a Novartis employee paid the 23 speaker an honorarium for an event at which the 24 speaker did not actually speak, would that 25 violate the Anti-Kickback Statute?</p>	<p>1 spent most of the time at the event socializing 2 with the other doctors?</p> <p>3 MR. GRUENSTEIN: Objection; lacks 4 foundation.</p> <p>5 A. It would depend upon what they 6 presented. So, for example, you have to have 7 indication, limitations of use, safety, all 8 right, you have to talk about the black box 9 warning, you have to have some promotional 10 content, all right. If they give core 11 information, you probably could have a shorter 12 speech. I don't know how fast the person's 13 talking, I don't know what -- you know, there's 14 facts that you'd have to look into.</p> <p>15 But if you're asking is it 16 prohibited for, after a legitimate speaker 17 program, for people to talk or laugh or network 18 with people, I don't think it is.</p> <p>19 Q. That's definitely not what I'm 20 asking.</p> <p>21 A. Oh, okay.</p> <p>22 MR. GRUENSTEIN: It did sound like 23 what the question was. Maybe you should read 24 the question back.</p> <p>25 MS. JUDE: Yeah, we can read the</p>
<p>1 MR. GRUENSTEIN: Objection. Are we 2 assuming that inducement caveat that you had 3 before?</p> <p>4 MS. JUDE: No.</p> <p>5 A. Oh, you're not assuming the 6 inducement? I thought you were assuming the 7 inducement for all the questions.</p> <p>8 Q. I'll start over.</p> <p>9 A. I'm sorry, I'm getting a little 10 tired.</p> <p>11 Q. We'll take another break soon.</p> <p>12 A. Okay.</p> <p>13 Q. Okay. Would a Novartis employee 14 violate the Anti-Kickback Statute if the 15 employee paid an honorarium to a speaker for an 16 event at which the speaker did not give any 17 presentation?</p> <p>18 MR. GRUENSTEIN: Objection; lacks 19 foundation.</p> <p>20 A. If they used -- if the -- if the 21 reason that they paid the honorarium was to get 22 the speaker to write prescriptions for Medicaid 23 and Medicare, yes.</p> <p>24 Q. Would your answer be the same if 25 that speaker delivered an abbreviated speech and</p>	<p>1 question back.</p> <p>2 A. I didn't answer it. I thought I 3 was answering it. I'm sorry, what was it again?</p> <p>4 Q. Let me reframe it. Would it 5 present an Anti-Kickback Statute concern to you, 6 as a compliance officer, if a Novartis employee 7 paid an honorarium to a physician speaker who 8 delivered a 15-minute long presentation, and 9 spent the majority of a speaker event 10 socializing with the other HCPs at the event?</p> <p>11 MR. GRUENSTEIN: I'm going to 12 object.</p> <p>13 A. It would depend upon the facts, but 14 that would be something that I would look into 15 to get more facts on. And the facts, as you 16 stated it, is enough for a trigger to 17 investigate it.</p> <p>18 Q. Is it enough for a trigger to 19 investigate if the speaker repeatedly speaks to 20 the same group of doctors on the same drug and 21 the same topic?</p> <p>22 MR. GRUENSTEIN: Objection; lacks 23 foundation.</p> <p>24 A. Yes. It -- it would be a trigger 25 to investigate. The issue that I had at</p>

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<p>1 Novartis is that I didn't know how to figure out 2 who all the attendees were, unless I was there. 3 Q. And -- 4 A. So the question you're asking me, I 5 couldn't at that time investigate because I 6 didn't know how or if it was possible within the 7 system for me to pull the attendees. There must 8 have been some way to pull attendees, but it was 9 not something that, in Q3 of 2008, we included 10 on our checklist.</p> <p>11 Q. If you had been able to pull the 12 names of the attendees at events, what would you 13 have done with those names?</p> <p>14 A. It would have been something 15 else --</p> <p>16 MR. GRUENSTEIN: Objection; calls 17 for speculation.</p> <p>18 A. It could have been something else 19 that we could have audited.</p> <p>20 Q. What about the scenario of the same 21 group of doctors attending the same events 22 causes a trigger for an investigation for you?</p> <p>23 MR. GRUENSTEIN: Objection; calls 24 for speculation.</p> <p>25 A. Well, again, it's audience fatigue.</p>	<p>1 on audience fatigue or what, at the time, we 2 would have called audience fatigue. 3 Q. At what point does audience fatigue 4 set in?</p> <p>5 MR. GRUENSTEIN: Objection. 6 A. My rule of thumb, for years, has 7 been two of the same deck per quarter, but I 8 also factor into it that, you know, you can take 9 one deck, but if a lipidologist is giving it 10 versus a cardiologist versus, you know, a 11 pediatric cardiologist is giving it, it gets a 12 different flavor; and so part of it depends upon 13 who the speaker is.</p> <p>14 Q. If there are three different 15 speakers giving the same deck -- strike that. 16 If there's a different speaker each time --</p> <p>17 A. Yeah.</p> <p>18 Q. -- after how many events on the 19 same deck should an attendee stop going?</p> <p>20 MR. GRUENSTEIN: Objection. Are 21 you asking what she thinks now or what she 22 thought in 2008?</p> <p>23 Q. I am asking what you think now.</p> <p>24 MR. GRUENSTEIN: Objection; 25 relevance.</p>
<p style="text-align: center;">Page 197</p>	<p style="text-align: center;">Page 199</p>

<p>1 But one of the advantages that I have now is 2 that the Government has brought suits in which 3 they've alerted people to this. And so, it 4 wasn't on my checklist back in 2008, but you can 5 bet your bottom dollar it's on my checklist now. 6 You know what I mean? 7 I used to think of it as audience 8 fatigue, but now it's an issue that people look 9 at. So when I look at it from today to try to 10 formulate an answer for what I was thinking 11 about in 2008, I kind of think that it's 12 something I should have looked at, but I didn't 13 even know how to pull that information. It 14 wasn't -- it wasn't included on the checklist.</p> <p>15 Q. Do you know whether anyone else at 16 Novartis had access to that information at the 17 time that you were there?</p> <p>18 A. The only person that -- the only 19 kinds of people that would have had access to 20 that would have been people that were in the -- 21 in the Cindy Cetani line, you know. We -- we 22 got information -- we would request information 23 that we wanted. But, in 2008, you know, it 24 sounds stupid now, but we weren't -- we didn't 25 think about, you know, having specific findings</p>	<p>1 A. What I think now is that two per 2 quarter, eight max per year, and, at more than 3 two per quarter, I would investigate it. At 4 more than -- hopefully, I would start the 5 investigation before it got to eight, but, at 6 eight, I would have some sort of a computer 7 trigger that would trigger that there had been 8 eight.</p> <p>9 Q. Would you put in any intermediate 10 triggers to alert you to the repeat attendance?</p> <p>11 A. Two. Two every quarter.</p> <p>12 Q. And I just asked you about what you 13 think for a limit now.</p> <p>14 What did you think about for a 15 limit at the time you worked at Novartis?</p> <p>16 MR. GRUENSTEIN: Objection; lacks 17 foundation.</p> <p>18 A. I really probably didn't have as 19 defined a view as I do now, but that's based 20 upon the fact that there are -- there are, you 21 know, CIAs out there now that help us figure out 22 what to do, that define what compliance should 23 look like, I didn't have that back in 2008, on 24 the number of times you can attend the same 25 deck. And so, I think that -- what I think I --</p>
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1 drop my children off at school, I tended to be,
 2 if not the first one, pretty much the first one
 3 in the office and the last one back. And so, I
 4 had more hours than was maybe typical, so I
 5 could handle more investigations. But the
 6 volume of investigations we had and the
 7 requirement to have a witness to be able to take
 8 notes and to -- to, you know, be a neutral
 9 listener, required us to have people and have
 10 space.

11 One of the things that Novartis did
 12 which was very accommodating was that, they
 13 hired a number of temps, such as Andrew
 14 Gallinger, who was a highly intelligent, highly
 15 educated person, who came in to be my witness.

16 When we had that first real lot of
 17 investigations that we had to do to catch up on
 18 the Maria Woods, I was able to hire two interns
 19 that literally helped, were my witness in
 20 investigations, set up the interviews, took the
 21 notes, wrote them up as a draft. You know, I
 22 think that they gave me a lot of resources.

23 Would I have liked to have more?
 24 Sure. Maybe I would have left before 7 o'clock
 25 at night, you know. Did I get the work done? I

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1 frame.
 2 My goal always was that, any
 3 complaint that came in, we touched it within
 4 three days. Sometimes a touch was looking at it
 5 and going, oh, come on, you know, this does
 6 not -- this is low priority, this is, you know,
 7 two people that don't get along, as opposed to
 8 some sort of a compliance issue. This is an HR
 9 issue as opposed to something else.

10 I hope we mostly met our goal. I
 11 hope that when we touched issues and read it
 12 quickly to triage it that we didn't make
 13 mistakes. I can't tell you that we didn't make
 14 mistakes. But I can tell you that everybody
 15 tried to touch something within three days.

16 MS. JUDE: I'm going to mark
 17 another exhibit for you, which is Nelson-Ling
 18 GX-5.

19 (Nelson-Ling Exhibit GX-5, Document
 20 Bates stamped NPCLSV_LIT1574840 through
 21 NPCLSV_LIT1574843, marked for identification.)

22 Q. This is Bates stamped ending in
 23 1574840 through 4843, and the top email is from
 24 David Hollasch, it's a Novartis email address to
 25 his Comcast email address, and he's forwarding

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1 got the work done.

2 Q. During the time you were at
 3 Novartis, was there ever a time that red flags
 4 about a particular event or sales representative
 5 were raised, but, due to lack of manpower, you
 6 were not able to investigate?

7 A. If a red flag was raised, I like to
 8 think that we got to each one, but we would get
 9 through a red flag in three days. So, for
 10 example, this Dr. [REDACTED] guy who calls up and
 11 goes, I'm calling the FDA, that would be a red
 12 flag and you'd call him back right away. Which
 13 is one of the reasons that you see, when I wrote
 14 this thing up, I called him back at, you know,
 15 and it listed the time, to show that, you know,
 16 I called the dude back, you know, as quick as
 17 possible, and I called him back, apparently, by
 18 myself, which showss, you know, how quickly, you
 19 know, we responded.

20 You know, there were issues which
 21 you saw that would be red flags, yellow flags.
 22 You know, however, we didn't flag it, but we
 23 were -- clearly were not so rigid that, you
 24 know, something that looked to be critically
 25 important, we didn't look into in a fast time

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1 other emails.

2 On the second page, I want to
 3 direct you to the email in the middle that's
 4 from David Hollasch on February 1, 2010 to you.
 5 Do you see that one?

6 A. In the middle?

7 Q. Yeah, the second page, where it
 8 says Natasha --

9 A. Oh.

10 Q. So David writes, "Natasha, the
 11 responsibility for speaker infraction follow-up
 12 should reside with Marketing or CSO, and I
 13 recommend that E&C not get involved even for a
 14 short time, as I don't think we budgeted the
 15 money to assume this responsibility. I could be
 16 wrong, as I was not involved with the budgeting
 17 process. Can you send me details on our budget
 18 for consultants? Since the budget was cut, I
 19 need to start developing an exit plan for Bob,
 20 Roberto and/or Rebecca."

21 Then on the next email, which is on
 22 the first page, you write back, "I have nothing
 23 on the budget at all. Julie told me that we got
 24 the same as 2009. Cindy said we got cut; I
 25 asked Cindy for it but got nothing."

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<p>1 Do you remember this exchange?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know what ultimately</p> <p>4 happened to the budget?</p> <p>5 A. The budget was cut. This was not</p> <p>6 under Julie Kane. This was when Cindy Cetani</p> <p>7 took over.</p> <p>8 Q. What was the budget that was cut</p> <p>9 for?</p> <p>10 A. It was cut for people to do</p> <p>11 investigations and auditing, and for us to</p> <p>12 have -- it was -- it was all our extra hands --</p> <p>13 many of our extra hands being cut.</p> <p>14 Q. Did this affect the number of</p> <p>15 investigations that Novartis was able to do?</p> <p>16 MR. GRUENSTEIN: Objection;</p> <p>17 leading.</p> <p>18 A. This was at the time period where</p> <p>19 it was clear I was no longer going to be working</p> <p>20 at Novartis, and I can't tell you what happened</p> <p>21 with investigations after I left.</p> <p>22 Q. When did it become clear to you</p> <p>23 that you were going to be leaving Novartis?</p> <p>24 A. In probably 2009.</p> <p>25 Q. And what prompted that realization</p>	<p>1 the operating unit level in a number of the</p> <p>2 different operating units. They formed --</p> <p>3 Novartis management formed committees to</p> <p>4 implement the remediation, many committees, that</p> <p>5 met constantly, discussing the same thing</p> <p>6 constantly, and we talked about it constantly.</p> <p>7 Now, Ludwig's get it done</p> <p>8 overnight, it was a year past.</p> <p>9 Q. I just want to make sure I</p> <p>10 understand. So you were focusing that answer on</p> <p>11 constantly discussing the same thing. Was there</p> <p>12 any action that was being implemented at the</p> <p>13 time that these discussions were happening?</p> <p>14 A. Yes. David Hollasch and I actually</p> <p>15 gave this presentation at the operating units.</p> <p>16 We enforced on it, we did ride-alongs on it, we</p> <p>17 -- we worked very hard to bring this</p> <p>18 multidisciplinary remediation through all the</p> <p>19 different functional groups. It was important</p> <p>20 to get the buy-in of legal, of Marty, of Cindy.</p> <p>21 It was many, many meetings, everyone with the</p> <p>22 goal to remediate Q3 2008 issues.</p> <p>23 Q. Are you familiar with the term</p> <p>24 speak-up culture?</p> <p>25 A. Yes.</p>
<p>1 for you?</p> <p>2 A. Mid-2009, Julie told me that I was</p> <p>3 not going to get the chief compliance officer</p> <p>4 position, that it was going to go to another,</p> <p>5 and it was clear at that point that we weren't</p> <p>6 accomplishing as much as one would hope in</p> <p>7 remediating for something on facts that were</p> <p>8 from Q3 2008.</p> <p>9 Q. How did it become clear to you at</p> <p>10 that point that compliance was not accomplishing</p> <p>11 as much as you or others had hoped?</p> <p>12 A. We were still giving the same</p> <p>13 speech. We were still giving iterations of</p> <p>14 GX-3.</p> <p>15 Q. By saying you're still giving</p> <p>16 iterations of the same speech, are you saying</p> <p>17 that you're not moving forward or are you saying</p> <p>18 something else?</p> <p>19 A. I was saying it wasn't moving</p> <p>20 forward.</p> <p>21 Q. And, what was the status of</p> <p>22 remediating the problems that the audit had</p> <p>23 uncovered?</p> <p>24 A. We made a number of positive steps.</p> <p>25 David Hollasch and I actually did training on</p>	<p>1 Q. What does that mean?</p> <p>2 A. Speak-up culture was -- there were</p> <p>3 a couple of different things that we did to try</p> <p>4 to get the message out, you know, to speak up,</p> <p>5 to file a complaint. And, one of the things</p> <p>6 that we did is, Julie let me spend money to go</p> <p>7 to a vendor who gave us a little, like, Rubik's</p> <p>8 Cube-type thing, it was a toy that you could</p> <p>9 play with, and it advertised speaking up, and it</p> <p>10 advertised the hotline and it talked about doing</p> <p>11 the right thing.</p> <p>12 I don't know if I have any of them</p> <p>13 any more, it's hard to explain, but it could</p> <p>14 open, it could fold, it was a toy, and we got</p> <p>15 thousands of those to be able to hand out to</p> <p>16 people, you know, when they did training, to try</p> <p>17 to impress upon them the importance of speaking</p> <p>18 up if you see that people aren't following the</p> <p>19 remediation training.</p> <p>20 Q. Did Novartis have a speak-up</p> <p>21 culture?</p> <p>22 MR. GRUENSTEIN: Objection; vague.</p> <p>23 A. I don't know.</p> <p>24 Q. Do you think that the efforts with</p> <p>25 the Rubik's Cube to popularize about speaking up</p>

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1 going to the speaker program, yes, to learn
 2 about Novartis products, but also to ask the
 3 question about a kind of patient and to talk --
 4 and the doctor could talk about it.

5 A lot of the discussions that
 6 happened afterwards, where there were medical
 7 discussions, a lot of times it would be those,
 8 or it would be people exchanging, you know,
 9 their kind of case experiences.

10 Q. I believe you testified that even
 11 when the presentations were 15 minutes, they
 12 could still be 15 minutes of education, is that
 13 correct?

14 A. They could.

15 MS. JUDE: Objection; misstates
 16 testimony.

17 A. Potentially could, yeah.

18 Q. And could that still be valuable to
 19 a doctor?

20 MS. JUDE: Objection; calls for
 21 speculation.

22 A. It could.

23 Q. You also testified about some work
 24 that you did in Tampa, do you recall that?

25 A. Yes.

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1 A. It was someone from Cravath, and I
 2 think her name was Nina Dillon, something like
 3 that.

4 Q. Was also WilmerHale involved,
 5 that's another law firm?

6 A. I know WilmerHale. I don't
 7 recall Wilmer -- I don't recall people other
 8 than Cravath.

9 Q. That's the way I like it, that
 10 people should only remember Cravath. For good
 11 things, though.

12 Did Cravath assist in the
 13 investigation?

14 A. As I recall, the answer is yes.

15 Q. By hiring -- strike that. Did you
 16 believe that Novartis was taking the allegations
 17 about Dr. [REDACTED] seriously?

18 MS. JUDE: Objection.

19 A. I was taking it seriously.

20 Q. What were you doing to show that
 21 you were taking it seriously?

22 A. Acting upon it, taking people down
 23 to Tampa, more than one person.

24 Q. And what was the outcome of the
 25 investigation, if you recall?

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1 Q. Was that involving Dr. [REDACTED]?

2 A. Yes.

3 Q. Now, was that a run-of-the-mill
 4 audit or was that an internal investigation?

5 A. It was a combo of the two.

6 Q. Let me ask the question slightly
 7 differently. What led you to look into
 8 Dr. [REDACTED], if you recall?

9 A. I'm not sure I recall. If you want
 10 me to guess, I am guessing.

11 Q. No guessing. Not necessary.

12 A. All right.

13 Q. Unless your lawyer wants you to
 14 guess. But I don't want you to guess.

15 A. Okay.

16 Q. Do you recall that there was a
 17 letter that was sent to Novartis about
 18 Dr. [REDACTED]?

19 A. No, I don't.

20 Q. Are you aware -- let me strike
 21 that. When you looked into -- strike that.
 22 When you investigated Dr. [REDACTED], did you do it
 23 with an outside counsel?

24 A. Yes.

25 Q. Who was the outside counsel?

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1 A. The outcome is that it was turned
 2 over to outside counsel.

3 Q. To further investigate, is that
 4 correct?

5 A. I do not know.

6 Q. Are you aware that Dr. [REDACTED] was
 7 taken off of the speaker list?

8 MS. JUDE: Objection; leading.

9 A. I did not know.

10 Q. Would you be happy to hear that
 11 Dr. [REDACTED] was taken off the speaker list?

12 A. I would be.

13 Q. You also talked about New Haven.
 14 Was that just -- was that an audit or an
 15 investigation?

16 A. It was an audit.

17 Q. And there, I believe you testified,
 18 you found no issues?

19 A. I do not recall finding issues.

20 Q. And then either North Carolina or
 21 South Carolina, was that an audit or
 22 investigation?

23 A. Audit.

24 Q. And again, I believe you testified
 25 that you didn't recall finding any issues?

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